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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,258	12/21/2001	Carsten Schelp	05552.1450	5022

22852 7590 08/25/2006

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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/024,258		SCHELP ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Deborah A. Davis		1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-22 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

1. Applicants' response to the Office Action mailed on February 7, 2006 has been acknowledged. Currently, claims 1-22 are pending and under consideration.

#### ***Information Disclosure Statement***

2. The IDS dated April 2002 will not be considered because the examiner did not receive a copy of the documents.

#### ***Claim Rejections - 35 USC § 102***

3. Claims 1-4 and 7-9 remain rejected under 102(b) for reasons previously set forth in the Office Action mailed 12-1- 2005.

#### ***Claim Rejections - 35 USC § 103***

4. Claims 5-6, 10-17 and 19-22 remain rejected under 103(a) for reasons previously set forth in the Office Action mailed 12-1-05.

#### ***Response to Arguments***

5. Applicant's arguments filed June 6, 2006 have been fully considered but they are not persuasive:
6. Applicant argues that the reference of Palomaki fails to teach the measurement limitation recited in independent claim 1. Applicant asserts specifically that Palomaki fail to teach "determining an L1-dependent measurement signal at a different time from an

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L2-dependent measurement signal or an L1 plus L2-dependent measurement signal, determining the L1-dependent measurement signal using a different measurement method than used to determine the L2-dependent measurement signal or the L1 plus L2-dependent measurement signal.” This argument have been fully considered but not found to be persuasive.

In response, a restriction requirement was set forth (dated 2-2-05) and applicant selected group I which included the examination of the limitation: **“L1-dependent measurement signal is determined at different times from L2 dependent measurement signal or L1 plus L2 dependent measurement signal”**. Palomaki teaches the measurement of L1 plus L2 by taking an absorbance (page 57, column 2, paragraph 5) measurement as recited in the alternative limitation of the claim. Although the examiner in the examination of the claims broadly recited what the entire claim 1 was drawn to, only the elected limitations were considered for examination. Therefore, Palomaki still anticipates claims 1-4 and 7-9.

7. Applicant argues that Palomaki combined with the reference of Marquardt do not teach or suggest all of the claim limitation of independent claim 19 and dependent claims 20-22. Applicant particularly argues that Palomaki does not teach a binding partner R3 (e.g., HRP-Mab2) associated with a member X of a specific binding pair that is recited in claim 19. These arguments have been fully considered but not found to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner relied on the teaching of Marquardt for the teaching of a member "XY" binding pair (i.e. biotin-avidin or avidin-streptavidin) which is commonly used in assay methods because they offer greater sensitivity by reducing background interference.

8. Applicant argues that the reference Marquardt fail to teach or even suggest all the limitations of claim 19. This argument have been fully considered but not found to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

9. Applicant argues that the reference Cragle does not teach or suggest any of the limitations of claim 1 and that the combination of Palomaki and Cragle fail to teach or suggest all of the limitations of claims 10-15. This argument have been fully considered but not found to be persuasive.

The reference of Cragle was relied on for its teaching of microparticles used as labels and considered to be a suspendable solid phase which is well known in the art to use microparticles in assay methods. Absent unexpected results, using microparticles as labels are known.

10. Applicant argues that the reference of Pitner does not cure the deficiencies of Palomaki because it does not teach all of the limitations of claim 1. Applicant further argues that Pitner is not directed to any of the limitations of claim 1 and Palomaki in combination with Pitner fail to teach or suggest all the limitations of Applicant's claims 16-17. These arguments have been fully considered but not found to be persuasive.

In response, the reference of Pitner was relied on for its teaching of energy transfer assays which are known in the art to detect binding events. The method permits qualitative and quantitative binding measurements, simplicity as well as sensitivity in measuring analytes, as recited in the Office Action. Absent unexpected results, using this form of detection in assay methods are known to the skilled artisan and is deemed obvious.

***Allowable Subject Matter***

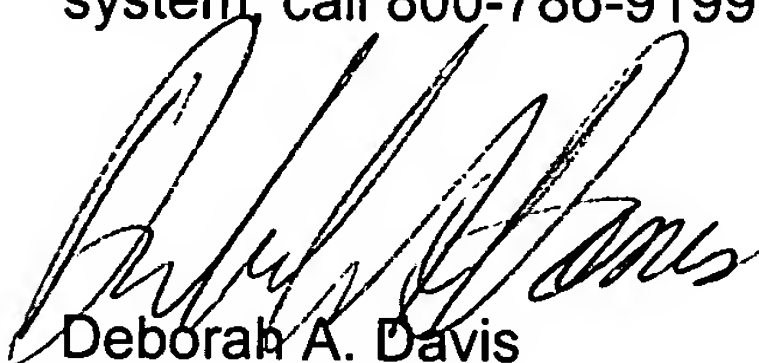
11. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McKelvey Terry can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Deborah A. Davis  
Patent Examiner  
August 2006



CHRISTOPHER R. TATE  
PRIMARY EXAMINER